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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------|---------------------|------------------|
| 10/759,695 | 01/16/2004 | Gerianne Tringali DiPiano | FEM 105 | 8448 |
| 23579 | 7590 | 05/19/2006 | EXAMINER | |
| PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361 | | | AHMED, AAMER S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |
| DATE MAILED: 05/19/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/759,695 | DIPIANO ET AL. | |
| | Examiner | Art Unit | |
| | Aamer S. Ahmed | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kline U.S. Patent Number 4,421,504. Kline discloses a method of transrectal drug delivery comprising breech filling a rectal applicator with 1mL or less of a pharmaceutical formulation (col. 4 line 29) in a rectal applicator, wherein the applicator (1) comprises an applicator barrel (5), wherein the barrel (5) comprises a medication chamber (8) at the proximal end of the applicator, wherein the medication chamber is capable of containing 1mL or less of a pharmaceutical composition; a plunger (6), wherein the plunger is insertable in telescoping relation to the applicator barrel (see figure 3); and a plunger tip (12), wherein the plunger tip (12) is at the end of the plunger (6); placing an applicator cap (310 on the applicator barrel; removing the applicator cap from the proximal end of the applicator barrel and inserting the applicator barrel into the patient's rectum; and wherein the pharmaceutical is a suppository (10) and wherein the method further comprises depressing the plunger to administer the pharmaceutical to the patient rectum and depressing the plunger until it reaches the end of the applicator barrel (see figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kline U.S. Patent 4,421,504 in view of Yeager et al.

Kline discloses the method as described above in reference to claim 6, but fails to explicitly disclose that the pharmaceutical formulation is in an amount effective to treat disorder and disease of the female urogenital system.

Yeager et al discloses a similar method in which the pharmaceutical formulation is in an amount effective to treat diseases of the female urogenital system (col. 2).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Kline et al by incorporating a pharmaceutical composition that is in an amount effective to treat diseases of the female urogenital system as taught by Yeager et al, in order to treat multiple diseases.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fallon et al U.S. Patent Number 6,027,471, in view of Yeager et al U.S. Patent Number 6,224,573.

Fallon et al discloses an apparatus for applying an agent comprising an applicator barrel (12), wherein the barrel comprises a medication chamber (18) at the proximal end of the applicator, wherein the medication chamber is capable of containing 1 mL or less of a pharmaceutical composition (19), and wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber (col. 2 line 37); a plunger (22), wherein the plunger is insertable in telescoping relation to the applicator barrel; a plunger tip (38), wherein the plunger tip is at the end of the plunger; and wherein the applicator comprise a flange (44).

Fallon fails to explicitly disclose a cap having a diameter that is effective at preventing insertion of the vaginal applicator into a vagina when the applicator cap is attached to the applicator barrel forming an air-tight seal with the applicator barrel and the plunger tip forms an air-tight seal with the applicator barrel.

Yeager et al discloses a similar device including an applicator cap (12) is attached to the applicator barrel forming an air-tight seal with the applicator barrel (col. 3) and the plunger tip forms an air-tight seal with the applicator barrel (col. 6).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Fallon et al by incorporating the cap and air-tight seal as taught by Yeager et al in order to prevent infection.

Response to Arguments

Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed



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